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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,896	08/01/2003	Klaus Preissner	06478.1491	9809

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,896	PREISSNER ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The restriction requirement mailed on 1/14/05 was incomplete. The instant restriction requirement supercedes the office action mailed on 1/14/05 in full. Applicant's traverse received on 8/1/05 is noted but is moot in view of the new restriction. Applicant is required to elect one of the following groups.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to a pharmaceutical preparation comprising RNA analogs, more specifically peptide nucleic acids, further comprising an activator for a plasma coagulation factor, classified in class 514, subclass 44.

II. Claims 1-3, drawn to a pharmaceutical preparation comprising RNA analogs, more specifically ribozymes, further comprising an activator for a plasma coagulation factor, classified in class 514, subclass 44.

III. Claims 1-3, drawn to a pharmaceutical preparation comprising RNA analogs, more specifically RNA aptamers, further comprising an activator for a plasma coagulation factor, classified in class 514, subclass 44.

IV. Claim 4, drawn to a method for promoting coagulation comprising administering the pharmaceutical preparation, classified in class 514, subclass 44.

V. Claims 5-7 and 12, drawn to a pharmaceutical preparation of one or more RNA degrading, inhibiting, or masking compounds and an activator for a plasma fibrinolytic, classified in class 514, subclass 44.

VI. Claims 8, 10 and 11, drawn to a diagnostic aids comprising detection of an increased plasma RNA content compared with healthy people, involving peptide nucleic acids, classified in class 514, subclass 44. Election of this group requires a further election of species as explained below.

VII. Claims 8, 10 and 11, drawn to a diagnostic aids comprising detection of an increased plasma RNA content compared with healthy people, involving ribozymes, classified in class 514, subclass 44. Election of this group requires a further election of species as explained below.

VIII. Claims 8, 10 and 11, drawn to a diagnostic aids comprising detection of an increased plasma RNA content compared with healthy people, involving aptamers, classified in class 514, subclass 44. Election of this group requires a further election of species as explained below.

IX. Claims 9 and 11, drawn to a diagnostic aid for quantitative or qualitative detection of coagulation factor VII-activating protease FSAP or its proenzyme, involving peptide nucleic acids, classified in class 514, subclass 44.

X. Claims 9 and 11, drawn to a diagnostic aid for quantitative or qualitative detection of coagulation factor VII-activating protease FSAP or its proenzyme, involving ribozymes, classified in class 514, subclass 44.

XI. Claims 9 and 11, drawn to a diagnostic aid for quantitative or qualitative detection of coagulation factor VII-activating protease FSAP or its proenzyme, involving RNA aptamers, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-III are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have not been disclosed as capable of use together and have different modes of operation. The inventions are each drawn to pharmaceutical preparations comprising separate and distinct compounds that act through unique pathways. Specifically, the inventions are drawn to compositions comprising peptide nucleic acids, ribozymes, and RNA aptamers, respectively. Each of the compounds is structurally and functionally unique, each requiring a separate search and examination. A search for any of the inventions of groups I-III would not necessarily return art against any of the other inventions. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups I-III are related to the invention of group IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case, the pharmaceutical preparation of groups I-III can be used in a blood sample for determining a patient's ability to coagulate blood, which does not involve the method of group IV.

The inventions of groups I-III are each unrelated to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have not been disclosed as capable of use together and have different effects. The inventions of groups I-III are each drawn to pharmaceutical preparations comprising an amount sufficient for **promoting coagulation** of natural or synthetic RNA or of one or more coagulation-promoting fragments of natural or synthetic RNA, RNA analogs such as peptide nucleic acids, ribozymes, or RNA aptamers, respectively. Alternatively, the invention of group V is drawn to a pharmaceutical preparation comprising an amount sufficient for **promoting fibrinolysis or inhibiting coagulation,** of one or more RNA-degrading or inhibiting compounds. The compositions of groups I-III have separate and distinct structural characteristics than the composition of group V, and further result in opposite effects. Additionally, groups I-III further comprise an activator for a plasma coagulation factor, whereas group V further comprises an activator of plasma fibrinolytic. The compositions are structurally and functionally unique. A search for any one of the inventions would not necessarily return art against any of the other inventions. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups I-III are each unrelated to the inventions of groups VI-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have not been disclosed as capable of use together and have different effects. The inventions of groups I-III are each drawn to pharmaceutical preparations, whereas the inventions of groups VI-XI are drawn to various diagnostic aids. The inventions have not been disclosed as capable of use together and involve separate and distinct structural and functional considerations. The diagnostic aids involve detection of an increased RNA content compared to healthy people, or qualitative or quantitative detection of coagulation factor VII-activation protease FSAP or its proenzyme. Neither of these are considerations of the pharmaceutical preparations of groups I-III. A search for any one of the inventions would not necessarily return art against any of the other inventions. To search more than one of these inventions in the same application presents a search burden.

The invention of group IV is unrelated to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have not been disclosed as capable of use together and have different effects. The invention of group IV is drawn to a method of promoting coagulation comprising administering a pharmaceutical preparation of groups I, II or III, whereas the invention of group V is drawn to an

unrelated pharmaceutical preparation of RNA degrading or inhibiting compounds in an amount sufficient to promote fibrinolysis or inhibit coagulation. The preparation of group V has the opposite effect than the method of group IV and the preparation of group V is not utilized in the method of group IV. A search for one of the inventions would not necessarily return art against the other invention. To search more than one of these inventions in the same application presents a search burden.

The invention of group IV is unrelated to the inventions of groups VI-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have not been disclosed as capable of use together and have different effects. The invention of group IV is drawn to a method of promoting coagulation comprising administering a pharmaceutical preparation of groups I, II or III, whereas the inventions of groups VI-XI are drawn to various diagnostic aids involving the detection of an increased RNA content compared to healthy people, or qualitative or quantitative detection of coagulation factor VII-activation protease FSAP or its proenzyme. Neither of these are considerations in the method of group IV. The inventions are separate and distinct. A search for the invention of group IV would not necessarily return art against any of the other inventions. To search more than one of these inventions in the same application presents a search burden.

The invention of group V is unrelated to the inventions of groups VI-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have not been disclosed as capable of use together and have different effects. The invention of group V is drawn to a pharmaceutical preparation, whereas the inventions of groups VI-XI are drawn to various diagnostic aids. The inventions have not been disclosed as capable of use together and involve separate and distinct structural and functional considerations. The diagnostic aids involve detection of an increased RNA content compared to healthy people, or qualitative or quantitative detection of coagulation factor VII-activation protease FSAP or its proenzyme. Neither of these are considerations of the pharmaceutical preparation of group V. A search for any one of the inventions would not necessarily return art against any of the other inventions. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups VI-VIII are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have not been disclosed as capable of use together and have different modes of operation. The inventions of groups VI-VIII are drawn to diagnostic aids involving the use of peptide nucleic acids, ribozymes, or RNA aptamers, respectively. Each of the diagnostic aids is structurally and functionally distinct based on the specific compound employed. Each of the compounds is structurally distinct and act through different mechanisms. A search for any one of the diagnostic aids would not necessarily return art against any of the other

diagnostic aids. It is the structure of each of the RNA analogs that determines its specific function. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups VI-VIII are each unrelated to the inventions of groups IX-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have not been disclosed as capable of use together and have different effects. The inventions of groups VI-VIII are drawn to diagnostic aids comprising detection of an increased plasma RNA content compared to healthy people, whereas the inventions of groups IX-XI are drawn to diagnostic aids comprising quantitative or qualitative detection of coagulation factor VII-activating protease or its proenzyme. These are completely separate and unique considerations. The diagnostic aids of groups VI-VIII have not been disclosed as capable of use with the diagnostic aids of groups IX-XI and function completely differently. A search for any one of the diagnostic aids of groups VI-VIII would not necessarily return art against any of the diagnostic aids of groups IX-XI. To search more than one of these inventions in the same application presents a search burden.

The inventions of groups IX-XI are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions have not been disclosed as

capable of use together and have different modes of operation. The inventions of groups IX-XI are drawn to diagnostic aids involving the use of peptide nucleic acids, ribozymes, or RNA aptamers, respectively. Each of the diagnostic aids is structurally and functionally distinct based on the specific compound employed. Each of the compounds is structurally distinct and act through different mechanisms. A search for any one of the diagnostic aids would not necessarily return art against any of the other diagnostic aids. It is the structure of each of the RNA analogs that determines its specific function. To search more than one of these inventions in the same application presents a search burden.

Because these inventions are distinct for the reasons given above and the search required for each subgroup is not required for the others, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention: Claim 8 is drawn to a diagnostic aid for detecting inter alia postoperative hypercoagulable states, complications of pregnancy, tumor status, acute myocardial infarction, or sepsis. Each of the conditions is unrelated and has

completely different etiologies. A search for any of these conditions would not necessarily return art against any other of the conditions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Hudson Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy Hudson Bowman
Examiner
Art Unit 1635

J.D. SCHULTZ, PH.D.
PATENT EXAMINER